K090046
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8. 510(k) Summary

FEB 27 2009

Applicant: Micro Therapeutics d.b.a.ev3® Neurovascular
9775 Toledo Way
Irvine, CA 92618
USA
Phone: +1-949-837-3700
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Date: Dec 17, 2008

Contact Person: Neelu Medhekar
Director, Global Regulatory Affairs

Proprietary Device Name: Concerto™ Detachable Coil System

Common Device Name: Vascular Embolization Device
(21CFR 870.3300, Product Code KRD)

Classification: Class II

Predicate Devices: Micro Therapeutics, Inc. Axium™ Detachable Coil System *cleared under K081465 on Aug 19, 2008;*
Micro Therapeutics, Inc. FX Detachable Coil System *cleared under K060747 on April 24, 2007 – marketed as the ev3® Axium™ Detachable Coil System*

Manufacturer: ev3® Neurovascular a division of ev3® Inc.
9775 Toledo Way
Irvine, CA 92618
USA

Note: Micro Theraputics Inc., does business as ev3® Neurovascular, which is a division of ev3® Inc. To simplify the product identification for the purposes of this submission, references will only be made to ev3® Inc.

8.1. Substantially Equivalent To:

The Concerto™ Detachable Coil System is substantially equivalent to the *ev3® Axium™ Detachable Coil System*, in terms of intended use, design, specifications, and materials. The Concerto™ Detachable Coil System uses

the same design, methods and materials in construction, packaging and sterilization as its predicate. The modification to the indications use statement has not altered the fundamental scientific technology of the Concerto™ Detachable Coil System.

8.2. *Description of the Device Subject to Premarket Notification:*

The Concerto™ Detachable Coil System consists of a platinum coil secured to a composite delivery wire and is compatible with a 2-marker band micro catheter and a mechanical detachment system. The Concerto™ coil configurations include bare platinum coils.

The Concerto™ Detachable Coil System consists of three components:
1- Implantable Coil,
2- Implant Delivery Pusher,
3- Instant Detacher (called the LRS (Linear Release System) actuator in K060747). The Instant Detacher is packaged and sold separately.

This submission localizes the indications for use statement for the Concerto™ Detachable Coil System for use in the peripheral vasculature. This indication is discussed further in Section 12.

8.3. *Indications for Use:*

The Concerto™ Detachable Coil System is indicated for arterial and venous embolizations in the peripheral vasculature.

8.4. *Performance Data:*

The Concerto™ Detachable Coil System is substantially equivalent to the Axium™ Detachable Coil System since the same methods and materials in construction, packaging and sterilization are used therefore no performance data were generated in support of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2009

ev3 Neurovascular
c/o Ms. Neelu Medhekar
Director, Global Regulatory Affairs
9775 Toledo Way
Irvine, CA 92618

Re: K090046
Concerto™ Detachable Coil System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II (two)
Product Code: KRD
Dated: February 4, 2009
Received: February 10, 2009

Dear Ms. Medhekar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7. Statement of Indications for Use

Indications for Use

510(k) Number (if known): K090046

Device Name: Concerto™ Detachable Coil System

Indications for Use:

The Concerto™ Detachable Coil System is indicated for arterial and venous embolizations in the peripheral vasculature.

Prescription Use __√_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090046

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